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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/942,055	08/29/2001	Robert Powers	16163-021002	8112	
26161 7	590 05/23/2005		EXAMINER		
FISH & RICHARDSON PC 225 FRANKLIN ST			MAHATAN, CHANNING		
BOSTON, MA 02110			ART UNIT	PAPER NUMBER	
			1631		

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	pplication No. Applicant(s)				
		09/942,055		POWERS ET AL.			
	Office Action Summary	Examiner		Art Unit			
		Channing S.		1631			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠	Responsive to communication(s) filed on 22	February 2005	.				
2a)□	This action is FINAL . 2b) This action is non-final.						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) 10-16,18,20-24,26-29,33-37 and 45-66 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 10-16, 18, 20-24, 26-29, 33-37, and 45-66 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.							
Applicat	ion Papers						
9)□	The specification is objected to by the Exami	ner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
2) Notice 3) Inform	e of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0	,) Interview Summary Paper No(s)/Mail Da	te	O-152)		
Paper No(s)/Mail Date 6) Other:							

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on 22 February 2005 has been entered.

Applicants' arguments, filed 22 February 2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66. Claims 1-9, 17, 19, 25, 30-32, and 38-44 have been canceled.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

NON-STATUTORY SUBJECT MATTER

Claims 10-15, 18, and 45-49 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a

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"Method for improving the accuracy of the mass determination of ions from a known class of biopolymers using a mass spectrometer of low mass accuracy".

M.P.E.P. section entitled "Nonstatutory Subject Matter" (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled "Statutory Process Claims" (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. Schrader, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See Diamond v. Diehr, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subjectmatter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also Alappat, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also id. at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The steps/processes of claims 10-15 and 45-49 are viewed as merely "mental" processes of performing mathematical operations. For example, instant claim 10 comprises the steps of: "(a) studying whether one or more chemical or biochemical test species binds a three-dimensional structure of an RGS4 polypeptide..."; and "(b) selecting a potential modulator...". Regarding

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claim 18 the instant claim recites the steps of: a) "identifying a substance that inhibits RGS4...by determining whether a candidate species binds a free RGS protein using a three-dimensional structure of an RGS4 polypeptide". However, the above claimed merely represent mathematical steps (i.e. in silico) and fails to present a clear indication of a concrete, tangible, and useful result. Therefore, because the claims consist solely of mathematical operations that do not result in something that is concrete, tangible, and useful the claimed invention is considered nonstatutory.

USE CLAIM

Claim 18 is rejected under 35 U.S.C. § 101 because the claimed recitation of "using a three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein", without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example Ex parte Dunki, 153 U.S.P.Q. 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 U.S.P.Q. 475 (D.D.C. 1966).

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE OF ENABLEMENT

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 are rejected under 35 U.S.C. § 112. first paragraph, because the specification, while being enabling for "a three-dimensional structure of the restrained minimized mean NMR coordinates of a free RGS4 polypeptide found

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in Table 2 including at least a core region of a free RGS4 protein" "from rat", does not reasonably provide enablement for "a three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein" (instant claims 10-16, 18, 20-24, 26-29, 33-37, 47-49, 52-54, 57-59, & 62-64) and "from any other organism" (instant claims 45, 46, 50, 51, 55, 56, 60, 61, 65, & 66, i.e. mammalian, human, etc.). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The specification states the following with respect to the enabled portion of the invention for "a three-dimensional restrained minimized mean structure of a free RGS4 polypeptide found in Table 2 including at least a core region of a free RGS4 protein" "from rat" (note Table 2 is found on pages 42-77 of the Specification):

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"RGS protein NMR studies and structural determinations herein were performed using an RGS4-core protein consisting of the conserved region of RGS4 (specifically that derived from rat) with a N-terminal methionine and a C-terminal hexahistidine tail. The three-dimensional solution structure determined for the RGS4-core protein, assuming the possibility of conservative amino acids changes and within +/- a root mean square deviation of the relative structural coordinates of the backbone atoms listed in Table 2 of not more than 1.5 Å (or more preferably, not more than 1.0 Å, or most preferably, not more than 0.5 Å), model the three-dimensional solution structures of other RGS4 proteins of any eukaryotic origin, including human RGS4. Further, because of the significant conservation of this domain among different RGS proteins, the three-dimensional structure of RGS4-core provided herein, again assuming conservative amino acids changes, and within +/- a root mean square deviation of the relative structural coordinates of the backbone atoms of the structure of not more than 1.5 Å (or more preferably, not more than 1.0 Å, or most preferably, not more than 0.5 Å), models the structures of the conserved region in other RGS proteins of all origins.

"Structural coordinates" are the Cartesian coordinates corresponding to an atom's spatial relationship to other atoms in a molecule or molecular complex. Structural coordinates may be obtained using NMR techniques, as described herein or as known in the art, or using x-ray crystallography as is known in the art. Alternatively, structural coordinates can be derived using molecular replacement analysis or homology modeling. Various software programs allow for the graphical representation of a set of structural coordinates to obtain a three dimensional representation of a molecule or molecular complex. The structural coordinates of the present invention may be modified from the original sets provided in Table 2 by mathematical manipulation, such as by inversion or integer additions or subtractions. As such, it is recognized that the structural coordinates of the present invention are relative, and are in no way specifically limited by the actual x, y, z coordinates of Table 2. The structural coordinates of Table 2 +/- a root mean square deviation from the conserved backbone atoms of the amino acids therein(or conservative substitutions thereof) of not more than 1.5 Å (or more preferably, not more than 1.0 Å, or most preferably, not more than 0.5 Å) define or embody the three-dimensional structure of free RGS4 (i.e., not complexed with another molecule) in solution. The RGS4 core conserved region contains a Gα binding site and an allosteric binding site." (page 17, lines 1-31)

"Table 2 lists the atomic structure coordinates for the restrained minimized mean structure of free RGS4 as derived by NMR spectroscopy" (page 18, lines 15-16)

In the field of protein NMR structure, it is well established that the utilization of NMR structures can serve as a good source of search models in crystal structure determination. However, said NMR structures possess several problems: 1) inaccuracies in NMR structures based upon short distance restraints; 2) imprecision of search models as a resultof limited data; and 3) difficulty in representing the relative reliability of atomic positions in an NMR model. Therefore, since the science of obtaining suitable NMR structures is underdeveloped, the obtainment of such structures is considered mainly a trial-and-error procedure. See, for example, Chen (Solution solution: using NMR models for molecular replacement. Acta Crystallographica

Section D. 2001. Volume D57, pages 1457-1461, particularly the Abstract; page 1457-1458, beginning on line 29). Therefore, while the skill in the art of NMR structures is high, the science of protein structure and obtaining predictable NMR structures is uncertain. Although, working examples are not, per se, required, the specification must provide an enabling disclosure for the invention as it is now claimed such that one of ordinary skill in the art could practice the invention without undue experimentation.

Therefore, because of the high level of quantity of experimentation necessary, the limited amount of direction present (by way working examples), the high level of complexity of the nature of the invention, the unpredictability of obtaining a NMR structures (i.e. threedimensional structure), and the broadly encompassing breath of the instant claims it would be undue experimentation to determine other NMR structures and conditions therein for the reasons noted above.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 and all claims dependent therefrom utilize the abbreviations "RGS4 and "RGS", respectively. Abbreviations in claims are considered vague and indefinite unless accompanied by the full name, usually in parentheses.

Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 10, 18, 20, 23, 26, and all claims dependent therefrom recite the limitation "whether the one or more chemical or biochemical test species binds the three-dimensional structure of the polypeptide" (independent claim 10)/ "whether a candidate species binds a free RGS protein using a three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein" (independent claim 18)/"whether the potential modulator inhibits or promotes the activity of RGS or RGS4/G complex" (independent claims 20, 23, & 26) which is considered vague and indefinite. With respect to instant claim 10 it is unclear if the criteria for selecting a potential modulator is based upon: 1) binding the three-dimensional structure of the polypeptide; or 2) not binding the three-dimensional structure of the polypeptide. Additionally, claims 18, 20, 23, and 26 (in view of claim 10) appear to be incomplete for omitting essential steps, wherein such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The omitted step appears to be: selecting a potential modulator. Note the "selecting" language would be unclear as to what Applicants' intend the selection criteria to represent similarly indicated in claim 10. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 18 provides for "using a three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-15, 18, and 45-49 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (NMR Techniques for Characterization of Ligand Binding: Utility for Lead Generation and Optimization in Drug Discovery. Biopolymers (Peptide Science). 8 October 1999, Volume 51, pages 221-243).

The following excerpt is from M.P.E.P. § 2106 Section VI "DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. § 102 AND 103" (particular emphasis on bolded areas) and is applied to the below 35 U.S.C. § 103 rejection, wherein the "the three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein" (instant claim 10 step (a) and claims 11-14, 45-46, & 49); 2) "RGS protein" (instant claim 10 step (b) and 47 & 48); and 3) "RGS4"/"RGS4 Gα complex" & "the three-dimensional structure of an RGS4 polypeptide including at least a core region of a free RGS4 protein" (instant claim 18) are considered "non-functional descriptive" material (i.e. mere arrangement of data; failing to satisfy the practical application requirement). Further, examples are provided for in the M.P.E.P. regarding situations of nonfunctional descriptive material.

As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed

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invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See Dann v. Johnston, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

All limitations concerning the type of data are given no patentable weight as they are considered to be non-functional descriptive material. As such, the claim limitations are considered to be limited to a memory storing any data, a processor in communication with memory, and capable of generating a three-dimensional model.

Moore reviews how NMR experiments to characterize ligand binding may be used to both screen for novel compounds during the process of lead generation, as well as provide Art Unit: 1631

structural information useful for lead optimization during the latter stages of a discovery program (Abstract; page 221, beginning on the left column line 9 to the right column line 16). The author describes methods for studying binding of compounds to a three-dimensional structure and to select said compounds (i.e. modulators) based upon binding (instant claim 10; page 229, beginning on the left column line 11 to the right column line 13, and Figures 9-16).

Thus, Moore makes it obvious to study any three-dimensional structure (i.e. derived by NMR) with any other three-dimensional structure to identify and select drugs (i.e. modulators; instant claims 15, 47, & 48) based upon binding.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: CSM

Date: May 12, 2005